AUG 0 8 2002

K022107

Attachment 7

510(k) Summary

CardioMedics, Inc.
CardiAssist Counterpulsation System Mark 3000

1.	Date Prepared:	June 27, 2002
2.	Submitter's Name: and Address	CardioMedics, Inc. 18872 Bardeen Avenue Irvine, CA 92612
3.	Contact Person:	Gary Clark, Director Quality and Regulatory Affairs CardioMedics, Inc. Ph: (949) 863-2500 x106 Fax: (949) 474-2446 Email: gclark@cardiomedics.com
4.	Device Name:	CardiAssist Counterpulsation System, Mark 3000
	Proprietary Name:	CardiAssist Counterpulsation System, Mark 3000
	Classification Name:	Device, Counter-pulsating, External
5.	Predicate Device:	The CardiAssist Counterpulsation System, Mark 3000, for treatment of CHF patients is substantially equivalent in function and intended use to the currently marketed CardiAssist ECP System cleared for market entry under 510(k) #K010261 (predicate device) as well as the Vasomedical EECP Therapy System Model TS3, cleared for market entry under 510(k) #K020857 on June 14, 2002.

6. Device Description:

The CardioMedics CardiAssist ECP System is a non-invasive circulatory assist device which provides increased circulation via external counterpulsation (ECP) for the treatment of ischemic heart disease including congestive heart failure, chronic angina pectoris, acute myocardial infarction and cardiogenic shock. External counterpulsation therapy improves cardiac function by enhancing the perfusion of the coronary vasculature, the development of coronary collateral circulation, and by reducing the workload of the heart.

The CardiAssist ECP System consists of the portable console containing the computer and pumps with a touch screen for user interface, an integral strip chart recorder, and leg cuffs and hoses. Additional components provided with the System include a finger plethysmograph and 3-lead ECG cable and leads.

This CardiAssist ECP System sequentially compresses the legs from the calves, thighs and buttocks, 40 milliseconds apart, by inflating three sets of flexible fabric cuffs during diastole. This results in movement of blood from the legs to the heart and entire upper body. Pressure, up to 310 mmHg, is applied with the timing and duration of each pulse, synchronized with the patient's ECG. When properly triggered, the pressure pulses applied to the vascular bed of the legs and buttocks transmit retrograde pressure through the entire vascular system. At the aorta, the aortic valve prevents retrograde flow into the left ventricle. Thus, a peak pulse of diastolic pressure occurs at or above systolic levels which increases the driving pressure in the coronary vasculature.

The difference between the new device and the predicate device is the indication. The indication is being expanded to include the treatment of congestive heart failure patients. The treatment of congestive heart failure patients with the CardiAssist ECP System does not require any changes in software, device design, or treatment regimen. The treatment of this patient population does not significantly change the safety or effectiveness of the device.

7.	Intended Use:	The CardioMedics, Inc., CardiAssist CounterPulsation System, Mark 3000, is intended to provide external counterpulsation (ECP) for the treatment of ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial infarction and cardiogenic shock. Use of this device may reduce pain and impairment associated with angina pectoris, congestive heart failure or myocardial infarction and may enhance coronary function.
8.	Comparison of Technological Differences:	Technological and functional characteristics of the modified device are identical to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 - 2002

CardioMedics, Inc.
c/o Mr. Gary Clark
Director, Quality and Regulatory Affairs
18872 Bardeen Avenue
Irvine, CA 92612

Re: K022107
Trade Name: CardiAssist CounterPulsation System Mark 3000
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counterpulsation Device
Regulatory Class: Class III (three)
Product Code: DRN
Dated: June 27, 2002
Received: June 28, 2002

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 8 – Statement of Intended Use

510(k) Number: K022107

Device Name: CardiAssist CounterPulsation System

Indications for Use:

The CardioMedics, Inc., CardiAssist CounterPulsation System is intended to provide external counterpulsation (ECP) for the treatment of ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial infarction and cardiogenic shock. Use of this device may reduce pain and impairment associated with angina pectoris, congestive heart failure or myocardial infarction and may enhance coronary function.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

PRESCRIPTION USE X OR OVER-THE COUNTER USE_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022107